

REMARKS

By this amendment, claims 4, 5, 8, and 10 are revised and claims 11-18 are added to place this application in condition for allowance. Currently, claims 1-18 are before the Examiner for consideration on their merits.

In the Office Action, the Examiner objected to the format of claims 4-10. Claims 4, 5, 8, and 10 have been duly amended so that each claim is in proper multiple dependent claim format. Since claim 10 has been made solely dependent on claim 1, claims 11-18 have been added. These claims correspond to original claim 10, but are now dependent on claims 2-9.

Turning now to the prior art rejection, the Examiner relies on two references to reject claims 1-3. Claims 1-3 are rejected under 35 U.S.C. § 102(b) based on WO/39945 to Kemp. Claims 1 and 2 are rejected under 35 U.S.C. § 102(e) based on United States Patent No. 6,737,084 to Crosby et al. (Crosby). Finally, claim 2 is also rejected under 35 U.S.C. § 103(a) based on Crosby.

It is respectfully contended that the rejections are in error and neither Kemp nor Crosby establish a *prima facie* case of anticipation or obviousness against the pending claims. The rejections are addressed below under the headings of the applied prior art.

KEMP

In rejecting claims 1-3, the Examiner has relied on 35 U.S.C. § 102(b) as the statutory basis for the rejection. However, the priority date for this application is April 16, 2002, which is before the publication date of May 23, 2002 of the Kemp publication. Therefore, the Examiner cannot rely on 35 U.S.C. § 102(b) to reject claims 1-3, but must

rely on 35 U.S.C. § 102(e). If the Examiner should maintain the rejection of the claims based on Kemp, clarification of the basis of the rejection is requested.

In the rejection, the Examiner contends that Kemp teaches all of the features of the invention. However, the Examiner has failed to address the limitation regarding the immiscibility of the vasodilator compound. Claim 1 states that the vasodilator active compound is disposed on the external condom surface in a form or within a composition that is immiscible with the claimed lubricant.

The rejection fails in its entirety to address this claim limitation. Granted that Kemp discloses the use of a composition, and that the fluid substance can include a substance having vasodilatory properties. This is the full extent of the disclosure of Kemp; there is no mention whatsoever of miscibility or immiscibility of the vasodilatory substance and the lubricant.

As the Examiner knows, in order to make a rejection based on anticipation, the applied reference must, either expressly or implicitly, teach each and every limitation of the claims. It is clear that there is no express disclosure that the lubricant of Kemp is immiscible. In addition, there is absolutely no basis to conclude that the claim limitation in question is somehow implied within the four corners of Kemp. Consequently, there is no legitimate basis to conclude that Kemp establishes a *prima facie* case of anticipation against claim 1, and the rejection must be withdrawn for this reason alone.

Further, there is no basis to conclude that claim 1 is obvious in view of the teachings of Kemp. The specification recognizes that if the lubricant and the vasodilator active compound are immiscible, the compound is localized substantially at the zone of application to the condom surface. This results in a resistance to translocation of the

active compound from the external surface to the adjacent portions of the internal surface, whereby the active compound is retained predominantly on the external surface and within the original zone of application, see page 2, lines 1-7.

In order for the Examiner to draw a conclusion of obviousness, some objective evidence must be present to support such an allegation. There is no basis in Kemp for that matter. Thus, any allegation of obviousness could only be the hindsight reconstruction of the prior art and could not be sustained on appeal. Therefore, claims 1-3 are patentable over the teachings of Kemp. Claims 4-18 are also in condition for allowance by reason of their dependency on claim 1.

CROSBY

The rejection based on Crosby suffers from the same ailments as the rejection based on Kemp. As with Kemp, the rejection fails to address the claim limitation regarding the immiscibility of the lubricant and vasodilator active compound, and Crosby cannot establish a *prima facie* case of anticipation for this reason alone. Crosby is only generally related to the invention in that there is a vague suggestion that the composition to be administered by a male condom can be combined with a lubricant, see col. 5, lines 30-35. The composition is also described as further comprising vasodilators, see col. 5, line 48. The invention of Crosby relates to make-up of the composition and is totally unrelated to the interaction between a lubricant and vasodilators. Lacking any teaching regarding these two components, Crosby cannot establish a *prima facie* case of anticipation against claims 1 and 2, and the rejection must be withdrawn.

Akin to the reasoning set forth above for the rejection based on Kemp, there is

also no basis in the prior art to conclude obviousness using the teachings of Crosby. This reference also lacks any hint or suggestion of a particular relationship between the vasodilator active compound and the lubricant, and there is just no reason to conclude that it would be obvious to make the two immiscible. Thus, claims 1 and 2 are patentably distinct from Crosby from an obviousness standard as well.

The rejection of claim 2 under 35 U.S.C. § 103(a) relates to the disposition of the composition, and even if this limitation were considered to be obvious, the Examiner is still without a legitimate basis to reject claim 1 under 35 U.S.C. § 103(a). Finally, claims 4-18 are also patentable over Crosby by virtue of their dependency on claim 1.

In summary, it is contended that the rejections of claim 1 under 35 U.S.C. § 102(b) or (e) are improper since neither Kemp nor Crosby teach each and every element of claim 1. Moreover, there is no justifiable basis to conclude obviousness from these two references, whether they are used alone or even in combination. Thus, claim 1 stands separate from them for patentability purposes.

Accordingly, the Examiner is respectfully requested to examine this application in light of this amendment and the arguments made above, and pass claims 1-18 onto issuance.

If the Examiner believes that an interview with Applicant's attorney would be helpful in expediting allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

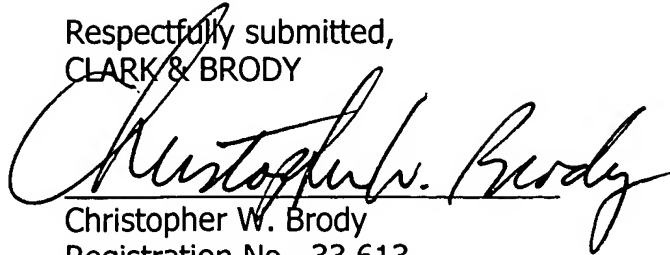
The above constitutes a complete response to all issues raised in the Office Action dated April 5, 2005.

Again, reconsideration and allowance of this application is respectfully requested.

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Respectfully submitted,
CLARK & BRODY

A handwritten signature in black ink, reading "Christopher W. Brody". The signature is fluid and cursive, with a large initial "C" and "B".

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